

K070423

MAR 28 2007

SECTION V. 510(k) SUMMARY

A. DEVICE NAME

Proprietary Name: TR Band
Classification Name: Tourniquet , Pneumatic
Common Name: Tourniquet

B. PREDICATE DEVICE

The predicate device is:

Product Name: Radstat Radial Artery Compression System
510k #: none
Establishment listing number: 1721504
Manufacturer: Merit Medical Systems

C. INDICATIONS FOR USE

The TR Band™ is a compression device to assist hemostasis of the radial artery after a transradial procedure.

D. DESCRIPTION

The TR Band is a tourniquet style device consisting of a plastic belt with hook and loop adjustable fastener on each end, two compression balloons, and an injection port. The device also contains a TR Band Inflator and an Air Volume Regulator.

The TR Band is placed around the patient's wrist and the hook and loop strap is connected. Once the introducer sheath is removed from the patient's wrist, pressure is applied to the patient's access site by inflating the compression balloons of the TR Band. Both compression balloons are filled at the same time while air is being introduced through the air injection port.

The balloons are inflated when air is injected into the air injection port by the TR Band Inflator. The TR Band inflator is a specially designed syringe for use only with the TR Band. A valve on the air injection port assures that the air remains within the compression balloons. The volume of air can be reduced or increased by use of the TR Band Inflator or the TR Band Air Volume Regulator. The TR Band Air Volume Regulator is an accessory device. The TR Band Air Volume Regulator is a smaller syringe (5 ml) compared to the TR Band Inflator (20ml syringe). This allows the physician to make fine adjustments to the pressure in the TR Band.

With the two compression balloons (large and small) the pressure is applied for efficient compression for haemostasis. The belt also has a support plate over the two compression balloons to assure that the balloons and belt conform to the contour of the wrist. The belt and compression balloons are made of clear plastic which allows the physician to view the access site during the haemostasis process.

The TR Band is for single use only.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The TR Band is operated manually or by a manual process.

F. DESIGN / MATERIALS

The design of the TR Band is similar to the predicate device. Differences in design between the devices do not raise any new issues of safety and effectiveness.

G. SPECIFICATIONS

The TR Band is available in two sizes. The sizes correspond to the length of the band. The larger size is available to accommodate individuals with larger size wrists. The specification for the device can be seen in the Engineering drawing section.

H. PERFORMANCE

The performance of the TR Band is substantially equivalent to the performance of the predicate device. The equivalence was shown through bench testing.

I. **Additional Safety Information**

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11135-1994 to provide a Sterility Assurance Level of 10^{-6} .

Blood contacting materials were tested in accordance with the test recommendations in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part I: Evaluation and Testing." The TR Band is classified as Surface Device, Breached or compromised surface, Limited Contact ($\leq 24h$). The blood contacting materials were found to be biocompatible.

J. SUBSTANTIAL EQUIVALENCE

The TR Band submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, and performance to the predicate device. Differences between the devices do not raise any issues of safety or effectiveness.

K. SUBMITTER INFORMATION

Name and Address

Terumo Medical Corporation
950 Elkton Blvd.
Elkton, MD 21921

Contact Person

Mr. Mark Unterreiner
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Date Prepared

February 9, 2007



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terumo Medical Corporation
% Mr. Mark Unterreiner
Senior Regulatory Affairs Specialist
West Plant
950 Elkton Boulevard
Elkton, Maryland 21921

MAR 28 2007

Re: K070423
Trade/Device Name: TR Band™
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: II
Product Code: DXC
Dated: February 9, 2007
Received: February 13, 2007

Dear Mr. Unterreiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

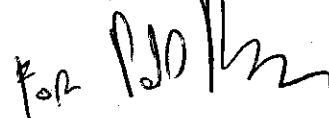
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Mark Unterreiner

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for P. N. Melkerson", written over the typed name.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070423

Device Name: TR Band™

Indications For Use:

The TR Band™ is a compression device to assist hemostasis of the radial artery after a transradial procedure.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070423

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